

NEORPORATED What Better feels like."

INTEGRATIVE THERAPEUTICS INC." NF Formulas + PhytoPharmica

Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 -Wilsonville, OR 9707 45 1 P: 503.582.8386 \* F: 503.582.0467

### ENZYMATIC THERAPY PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920,469.1313 F: 888.570.6460 (Enzymatic)

May 20, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Dietary supplement to promote bone health*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

LET 16269 97S 0162

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/20/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



What Better feels like."

INTEGRATIVE THERAPEUTICS INC."

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Tyler Encapsulations \* Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 - F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 \* F: 888.570.6460 (Enzymatic) P: 920.469.9099 \* F: 920.469.4418 (Phyto)

May 20, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Magnesium activates enzymes that	Magnesium (as magnesium oxide and
Plus	help form new calcium crystals.*	magnesium aspartate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/20/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Calcium is important - more than 99% of the body's calcium is found in the bones and teeth. But the body also needs vitamin D to properly use calcium and phosphorus.*	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Vitamin D3 (as cholecalciferol)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/20/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



### ENZYMATIC THERAPY NCORPCRATED

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What Better feels like." May 20, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Supports and maintains healthy bones and bone structure.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCI, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCI) (vitamin B1), Vitamin B6 (as pyridoxine HCI), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone — 7)

By: Kuldlilli

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/20/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux Chief Financial Officer

OsteoPrime Plus 4e



### ENZYMATIC THERADY MORPORATED

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 & F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 20, 2005

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	The body needs vitamin D to utilize calcium and phosphorus properly for building strong bones and teeth.*	Phosphorus (as tricalcium phosphate), Vitamin D3 (as cholecalciferol)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Title: Senior Vice President of Scientific Affairs

Date: 5/20/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.

Michael P. Devereux

Chief Financial Officer

OstcoPrime Plus 5:



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# ENZYMATIC THERAPY & PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 23, 2005

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RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Vitamin K aids the production of	Vitamin K (as phytonadione)
Plus	osteocalcin, the supporting structure	
	on which calcium crystallizes in bone.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date

5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux

Chief Financial Officer



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Manganese is needed for bone	Manganese (as manganese aspartate)
Plus	mineralization and connective	
	tissue synthesis.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux

Chief Financial Officer



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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

### ENZYMATIC THERAPY **PHYTOPHARMICA**

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 23, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS:
OsteoPrime®* Plus	Studies show zinc, strontium, vitamin B6, vitamin C, silicon, copper, and boron also help form the connective structures in bones.*	Silicon (as magnesium trisilicate), Strontium (as strontium chloride), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Zinc (as zinc picolinate), Copper (as copper gluconate), Vitamin B6 (as pyridoxine HCI)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.



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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	OsteoPrime Plus, formulated by Jonathan Wright, M.D., provides a balanced combination of these important nutrients to support and maintain healthy bones.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

kralint

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Vitamin K attracts calcium to	Vitamin K (as phytonadione), Natto
Plus	bone tissue.*	(fermented soybeans containing 45 mcg of
		Vitamin K2 as Menaquinone – 7)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

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Sincerely,



### **ENZYMATIC THERADY** MCDRPORATED

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Healthy bones need:	Silicon (as magnesium trisilicate), Strontium
Plus	Manganese, zinc, strontium,	(as strontium chloride), Boron (as boron
	vitamin B6, vitamin C, silicon,	Krebs cycle chelates), Vitamin C (ascorbic
	copper and boron to aid bone	Acid), Zinc (as zinc picolinate), Copper (as
	and connective tissue	copper gluconate), Vitamin B6 (as pyridoxine
	development.*	HCI). Manganese (as manganese aspartate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has statements are truthful and not misleading. substantiation that th

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

3/23/05

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	OsteoPrime Plus provides a balanced combination of important nutrients to support and maintain healthy bones in women and is targeted to work especially well for women during menopause.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCI, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCI) (vitamin B1), Vitamin B6 (as pyridoxine HCI), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

By: KILLULT

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Lifestage 3 gives you a full range of nutritional support, keeps those bones healthy and strong and controls menopausal symptoms.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCI, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCI) (vitamin B1), Vitamin B6 (as pyridoxine HCI), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone — 7)

BV: KUHCILL

Robert C. Doster

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

What Better feels like."

May 24, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	OsteoPrime Plus provides a balanced combination of important nutrients to support and maintain healthy bones in women and is targeted to work especially well for women during menopause and postmenopausal years.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

KIRBILA

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



NECHPORATED

What Better feels like."

May 24, 2005

INTEGRATIVE THERAPEUTICS INC."

NF Formulas « PhytoPharmica

Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503:582.8386 + F: 503.582.0467

### ENZYMATIC THERAPY & Phytopharmica\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 \* F: 888.570.6460 (Enzymatic) P: 920.469.9099 \* F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Enzymatic Therapy's Lifestage System is a 3-Stage system for every woman's life! Each system includes a stage-specific multivitamin, targeted bone health support and relief for the uncomfortable symptoms of PMS, perimenopause and menopause.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



INCORPORATED

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May 24, 2005

INTEGRATIVE THERAPEUTICS INC. The NF Formulas & PhytoPharmica

NF Formulas « PhytoPharmica Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 - F: 503.582.0467

### ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Take Control of: Hot flashes, Night sweats, Low energy, Mood swings, Restless sleep, Irritability, Calcium needs, Inadequate vitamin levels*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

By: \_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely



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INTEGRATIVE THERAPEUTICS INC."

NF Formulas « PhytoPharmica Tyler Encapsulations « Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 24, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

PRODUCT	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM
NAME OsteoPrime®* Plus	Offers a balanced combination of nutrients to support and maintain healthy bones, including calcium for strong bones and teeth; magnesium to help form new calcium crystals; and zinc, vitamin C, and boron to help form the connective structures of the bone*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCI, Magnesium (as magnesium oxide and magnesium aspartate), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCI) (vitamin B1), Vitamin B6 (as pyridoxine HCI), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone — 7)

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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What Better feels like."

INTEGRATIVE THERAPEUTICS INC.

NF Formulas « PhytoPharmica
Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467

# ENZYMATIC THERAPY' & PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 24, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

	AND THE PARTY OF T		
PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS!	
OsteoPrime®* Plus	And healthy bones need a variety of nutrients to preserve adequate mineral mass, and maintain strong supporting structures.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone — 7)	

BY: FLICHT

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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INTEGRATIVE THERAPEUTICS INC.

NF Formulas - PhytoPharmica
Tyler Encapsulations - Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

# ENZYMATIC THERAPY & PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 24, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Calcium is primary building material for bones - more than	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs
	99% of the body's calcium is found in the bones and teeth.*	cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate),

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: FLICILE

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: (5/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



### ENZYMATIC THERADY INSORPORATED

INTEGRATIVE THERAPEUTICS INC." NF Formulas » PhytoPharmica

Tyler Encapsulations « Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 \* F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 . F: 888.570.6460 (Enzymatic) P: 920.469.9099 \* F: 920.469.4418 (Phyto)

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May 25, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Magnesium is vital to the ongoing	Magnesium (as magnesium oxide and
Plus	process of bone formation.*	magnesium aspartate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

5/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.